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Director, CSRA

General Matter Report
DEA Internet Pharmacy Initiative 07/05

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DATE ▲	UPDATED ▲	SUBJECT ▲	AUTHOR ▲
12/07/05	12/07/05	Status	Mays S.

Excessive/Suspicious Order Review policy, procedures and related forms a complete and approved by legal. Copies saved to this matter and in CSRA Internal Policy Manual. Matter closed pending further information.

12/07/05 12/07/05 Status Mays S.

Mays attended a meeting at DEA headquarters in Washington DC on 8/10/05. During the meeting DEA provided a presentation of DEAÃ¢??s perception of the growing Internet Pharmacy problem in the US. DEA plan: to bring in many of the large wholesale distributors for discussions on how to identify illicit Internet pharmacy operations. DEA provided a binder to A that included the presentation, past case history regarding civil and crimin actions taken against illicit Internet Pharmacy operations, and a proposed DEA questionnaire to be utilized for due-diligence of Internet Pharmacies. DEA also indicated that they could take action against a distributorsÃ¢?? registration if they determined the registration was not in the public intere i.e. the distributor was not maintaining effective controls against diversion controlled substances into other than legitimate medical channels.

On 9/19/05 ABC conducted a follow-up conference call with DEA to further discuss this issue. Mary Fox, Chris Zimmerman, Steve Mays and Tom Suddath participated in the call. DEA explained their concerns with illicit Internet pharmacies and physicians that participate in this activity. DEA is also looking to distributors to conduct their due diligence of customers purchasing large quantities of controlled substances and make a business decision to stop supplying the customer if it is determined that they may b involved in illegal internet pharmacy operations. CSRA is currently developing procedures for investigating possible excessive or suspicious purchasing activity of customers and identifying those that may be involve in illegal activity.

07/21/05 12/07/05 Description Mays S.

On 7/21/05 Mike Mapes, DEA Director of e-commerce contacted Steve Ma and requested a meeting with ABC at DEA headquarters in Washington DC to discuss Internet pharmacy issues. Mapes stated that Illegal Internet pharmacy practices are becoming widespread and DEA is looking for cooperation from industry to address the problem.

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AM-WV-01079

AmerisourceBergen

EXCESSIVE SUSPICIOUS CONTROLLED SUBSTANCES ORDERS

Policies and Procedures

Policy Number: **S&RC 5.1**		Effective:	October 1, 2005
Written/revised by: Steve Mays / Cathy Marcum		Revised:	January 31, 2006

PURPOSE

To establish a process to monitor and report suspicious orders and/or unusual transactions under the guidelines of all local, state, and federal laws and regulations applicable to this corporation and it's Distribution Centers (DC).

POLICY

21 CFR 1301.74(b): *The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*

A **suspicious order** is any order that is of unusual size or frequency or that deviates substantially from the normal pattern. The DCM is responsible for ensuring that all associates are thoroughly familiar with the procedures for recognizing and reporting such orders.

The DCM and/or Compliance Coordinator must have thorough knowledge of and be able to articulate how, when and where their DC is reporting suspicious orders to DEA.

Reporting of suspicious orders is automated to report possible suspicious or unusual transactions to the DEA electronically on a daily basis. The DCM or Compliance Coordinator must review, sign and date this report on a daily basis. On a quarterly basis, contact your local DEA office to ensure they are receiving daily reports.

It is imperative that each DCM understand that these computer reports do not relieve them of their responsibility to report suspicious orders, especially large single orders. Remember, the computer reports reflect sales only and do not necessarily reflect the quantities of items ordered. It is the order that is suspicious, not the actual shipment. Remember, all contact with DEA must be recorded on a Government Contact Form (CSRA Form #2).

Listed Chemicals

Each DC must report suspicious orders and/or unusual transactions involving listed chemicals to their local DEA office. Suspicious orders include transactions involving "extraordinary quantities," transactions involving an uncommon method of payment or delivery, and any other types of sales that would indicate that the purchased product might be used to manufacture illicit substances.

This notification should be by telephone and then followed with a written report within 15 days of notification. A **Regulated Chemical Transaction Report, CSRA Form #21** must be used for this notification.

AmerisourceBergen

POSSIBLE EXCESSIVE/SUSPICIOUS ORDER REVIEW

Policies and Procedures

Policy Number: **CSRA 2.12**
Written/revised by: Steve Mays

Effective: December 1, 2005
Revised:

PURPOSE

To ensure compliance with applicable state and federal regulations, AmerisourceBergen Corporation (ABC) has designed this program to review the ordering activity of its customers to identify the existence of possible excessive or suspicious orders of controlled substances and listed chemical products.

POLICY

The CSRA department and Distribution Center Management will be responsible for identifying potential excessive or suspicious customer ordering activity of controlled substances and/or listed chemical products and will initiate appropriate investigative steps when possible indicators of such activity are identified. As part of this effort, all ABC Associates are expected to report to the CSRA department any information regarding potential excessive or suspicious orders of controlled substances and/or listed chemical products by any ABC customer.

OVERVIEW OF PROCEDURE

Investigations into possible excessive/suspicious orders may be initiated through the following three sources:

A. Possible Excessive / Suspicious Order Monitoring Program
B. Notification by DEA
C. Notification by Distribution Center

A. Possible Excessive / Suspicious Order Monitoring Program

The following procedures will be conducted as part of the Suspicious / Excessive Order Monitoring Program:

1. The CSRA department will establish appropriate guidelines and parameters of monthly ordering activity for certain controlled substances and listed chemical products.

2. At the beginning of each month, the CSRA department will generate a "Possible Excessive / Suspicious Order Report" to identify ABC customers whose ordering activity for the preceding month are in excess of the guidelines and parameters of

monthly ordering activity established by the CSRA department. This report will be reviewed by a CSRA Specialist and the CSRA Manager.

3. The CSRA Manager will identify customers whose purchasing activity warrants further review.

4. A one year purchase history for controlled substances and listed chemical products will be reviewed by the CSRA manager for each customer identified in step #3.

5. The CSRA Manager will consult with the appropriate DC and account manager regarding the customer's ordering patterns. If the CSRA Manager determines that further investigation is appropriate, additional investigative steps will include:

a. Obtaining all agreements and contracts the customer has with ABC;
b. Obtaining a copy of the customer's file ; and
c. Utilizing ABC's "Pharmacy Questionnaire (CSRA I Form 590), the responsible account manager for the customer will conduct a site visit of the customer and return the completed CSRA I Form 590 to the CSRA Manager within one (1) week.

6. The CSRA Manager will conduct a final review with the CSRA Director after all relevant information has been obtained in order for the CSRA Director to determine the appropriate resolution of the investigation, which, following consultation with the Legal Department, may include immediate cessation of sales of controlled substances and/or listed chemical products to the customer.

7. If sales of controlled substances and/or listed chemicals to the customer are to be continued, such sales will be conditioned upon the customer signing one of the following documents:

a. Non-Internet Pharmacy Agreement (CSRA I Form 590a)
b. Internet Pharmacy Compliance Agreement (CSRA I Form 590b)

Non-Internet Pharmacy Agreement
If the customer does not participate in an internet pharmacy operation, an authorized customer representative will be required to sign a Non-Internet Pharmacy Agreement (CRSA I Form 590a).

Internet Pharmacy Compliance Agreement
If the customer participates in an internet pharmacy in which controlled substances are dispensed, an authorized customer representative will be required to sign an Internet Pharmacy Compliance Agreement (CSRA I Form 590b).

8. If the customer signs the applicable agreement, the signed agreement will be maintained in the matter file and the account will remain open and be closely monitored.

9, If the customer declines to sign the applicable agreement, CSRA will contact the VP / DC Manager of the appropriate ABC distribution center and the Legal Department

and request that the customer's ability to purchase controlled substances and listed chemical products be suspended immediately and indefinitely.

B. Notification by DEA

If ABC receives notice from the DEA of possibly excessive or suspicious purchasing activity, CSRA will follow Steps 4 through 9 described above. DEA will also be notified upon completion of the investigation and will be advised of the disposition of the account.

C. Notification by Distribution Center

If an ABC Distribution Center receives notice of possibly excessive or suspicious Purchasing activity, CSRA will follow Steps 4 through 9 described above.

AmerisourceBergen Corporation
Attn: Corporate Security & Regulatory Affairs Dept.
1300 Morris Drive
Chesterbrook, PA 19087

To Whom It May Concern:

Until it provides written notice to AmerisourceBergen Corporation, _____ ("Pharmacy") will order and dispense controlled substances in Schedules II, III, IV, and V from AmerisourceBergen Corporation for above referenced pharmacy's walk-in patients only, and not for Internet / Mail Order pharmacy business.

Pharmacy hereby confirms that the quantity of controlled substances ordered will not be excessive and will be consistent with the actual demand by such patients.

Respectfully,

Signature: _____

Full Name (Print): _____

Title: _____

Date: _____

AmerisourceBergen

INTERNET / MAIL ORDER PHARMACY COMPLIANCE AGREEMENT

_____ ("Pharmacy") agrees that it will fully comply with the following requirements for pharmacies involved in Internet and/or Mail Order business for dispensing of drugs. Specifically, Pharmacy agrees that prior to filling the prescription, it will:

- Confirm with the DEA that the prescriber has a valid DEA registration when controlled substances are involved and that the registration is for the state in which the prescriptions are written;
- Confirm with the state medical licensure authority that the prescriber is licensed and in good standing in the state from which he/she is prescribing;
- Verify the validity of the prescription with the physician's office by phone;
- Verify that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice;
- Adhere to all applicable laws, rules, regulations, ordinances, and guidance of the states into which it dispenses prescriptions and the states in which it is licensed.

Furthermore, Pharmacy agrees that if any of the following factors exist, it is best to assume the transaction may not be valid and that Pharmacy will seek approval from DEA and/or the appropriate state regulatory authority prior to filling the prescription or will discontinue filling prescriptions from the physician and/or for the patient in question:

- Numerous or excessive numbers of prescriptions written for the same drugs, same amounts and same period of time by the same or a few of the same physicians, most of whom are located in different states than the patient;
- Numerous or excessive numbers of prescriptions written for controlled substances for the same person or for various persons by the same or a few of the same physicians, often located in different states than the patient;
- Numerous prescriptions written by the same or a few of the same physicians for patients who are all or nearly all in other states.

Pharmacy also acknowledges that AmerisourceBergen is required by 21 CFR 1301.74(b) to report suspicious orders of controlled substances to the Field Diversion Office of the DEA and AmerisourceBergen may provide a copy of this Agreement to the DEA or any other state or federal agency, entity, authority or board.

Pharmacy agrees that any failure to comply with this Agreement may result in AmerisourceBergen immediately terminating its Prime Vendor Agreement and/or relationship, in whole or in part.

Agreed to by a duly authorized officer, partner, or principal of Pharmacy.

Signature: _____

Full Name (print): _____

Title: _____

Date: _____

PHARMACY QUESTIONNAIRE

A. DECISION QUESTIONS (To be completed during on-site visit)

1. Customer Name: _____
2. Customer Address: _____
3. Customer DEA #: _____
4. Has the distributor physically inspected the pharmacy? Yes____ No____
5. Does the pharmacy have any other licensure (wholesale, repackager, etc...)?
   Yes____ No____ If so, obtain copies.
6. Does the pharmacy accept walk-in customers?
   Yes____ No____ If so, what percentage of total business? _____%
7. Is the pharmacy licensed for sales in all required states? Yes____ No____
8. Which state(s) does the pharmacy ship into? _____
9. Are Prescriptions written by physicians located in the State in which the patient resides?
   Yes____ No____
10. Does the pharmacy purchase a wide range of drug products from the distributor?
    Yes____ No____
11. Do controlled substances constitute an unusually large percentage of the pharmacy's purchases? Yes____ No____ If so, what percentage? _____%
12. Has the pharmacy requested to pick up (Will Call) orders rather than have them delivered?
    Yes____ No____
13. Is the pharmacy ordering more than 3,000 dosage units of phenetermine a month?
    Yes____ No____ If so, how much and why? _____
14. Is the pharmacy ordering more than 5,000 dosage units of hydrocodone combination products a month? Yes____ No____ If so, how much and why? _____
15. Is the pharmacy ordering more than 5,000 dosage units of Alprazolam a month?
    Yes____ No____ If so, how much and why? _____
16. Does the pharmacy have a web site or are they related to a web site?
    Yes____ No____
17. If the pharmacy has a web site or is related to a web site:
    a. What is the address?_____
    b. Are reasonable retail prices listed on the web site? Yes____ No____

c. Is there a patient medical history questionnaire on the web site? Yes____ No____

d. Does the prescribing doctor perform a physical exam of each patient? Yes____ No____

e. Does the web site accept third party payment (i.e. insurance) for Internet prescriptions? Yes____ No____

f. Does the web site offer to sell drugs without a prescription? Yes____ No____

18. Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites™) certified? Yes____ No____

19. Does a third party pay the distributor for the drugs? Yes____ No____

20. Attach photograph of pharmacy building (inside & outside).

OTHER COMMENTS/OBSERVATIONS: